

### **REMARKS**

This is in response to the non-final Office Action dated December 28, 2007.

Independent claim 1 and its dependent claims 2-7 and 14-17, independent claim 10 and its dependent claims 11-13, and independent claim 19 and its dependent claims 20-22, are currently pending and at issue.

#### **Claim Rejection – 35 U.S.C. § 103(a)**

The Examiner has rejected claims 1-7, 10-17 and 19-22 under 35 U.S.C. § 103(a) as being unpatentable over Summerbell et al. (BMJ 317 1998 p. 1478-89) in view of Milk in Wikipedia, Dietary Supplement Fact Sheet: Calcium, and Ask A Scientist: IU. Applicants contend that the present invention is distinct from Summerbell, which does not disclose, teach or suggest any of the elements of independent claims 1, 10 or 19.

The Office Action states that “[p]rosecution is reopened in view of a finding of new grounds of rejection.” Applicants disagree with this contention. The same arguments have been presented previously and have been overcome. Summerbell formed the basis for rejections in Office Actions dated January 3, 2006 and June 21, 2006. Now, as in the previous Office Actions, the substance of the argument is that it would have been obvious to one of ordinary skill to formulate a high calcium diet for obese patients to achieve the beneficial effect of a reduction in body fat content. The references Milk in Wikipedia, Dietary Supplement Fact Sheet: Calcium, and Ask A Scientist: IU add nothing to the argument; indeed, they add nothing that was not already disclosed in the specification itself. Applicants fail to see what will be accomplished by having Applicants re-present the same arguments to address the same issues when those arguments have already been considered and deemed persuasive by the PTO. Nevertheless, Applicants address the arguments once again.

The Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143. Each cited reference does not teach or expressly or impliedly suggest any of the limitations set forth in the present claims. There is no motivation to combine the reference with other knowledge. There would not be a reasonable expectation of success.

In addition, the Applicants previously submitted evidence showing the present invention's unexpected results, which has led to a significant shift in the scientific community and the food

industry, which has supported and endorsed the methods of the present invention leading to significant recognition and commercial success.

As set forth in the introduction, Summerbell tests diets with high compliance and hence good for weight loss. The study in Summerbell was designed to test the hypothesis that prescription of a simple and novel diet would result in higher levels of compliance and weight loss. In fact, Summerbell associates higher weight loss for the milk groups diet because that diet is "simple but much less boring and patients were more likely to comply with it" than with the conventional diet. Indeed, Summerbell is "not advocating milk only as a general long term reducing diet for obese outpatients, because in the long term it will cease to be novel and compliance will fall." Summerbell concludes that "[p]robably the best strategy is to rotate diets..." These statements would lead one away from the teaching of the present invention, which involves administering one or more calcium-containing products, e.g., monthly. The point to extrapolate from Summerbell is that one could use any type of food regimen or diet so long as it is simple and less boring to ensure compliance. Nowhere in Summerbell is it disclosed that calcium directly induces weight loss and/or increases the metabolic consumption of adipose tissue, as opposed to indirectly causing a dieter to lose weight by reducing overall caloric intake.

Furthermore, Summerbell does not disclose, teach or suggest administering one or more calcium containing product(s) and restricting caloric intake produces a weight-related benefit attributable to the calcium. The Examiner fundamentally mischaracterizes the language of the claims, disregarding the claim language attributable to the calcium . . . ." When this language is considered, it is clear that the claims at issue are patentable over Summerbell, because Summerbell does not disclose, teach or suggest a weight-related benefit attributable to the calcium. Indeed, Summerbell offers no basis for concluding that the weight loss is attributable to any of the numerous nutrients in milk, let alone calcium in particular. Instead, Summerbell teaches away from a direct induction of weight loss attributable to calcium by ascribing the observed weight loss to the simplicity and novelty of the diet, and also by stating that the authors are "not advocating milk only as a general long term reducing diet for obese outpatients . . . ."

The Examiner's calculations regarding the number of servings of dairy or the amount of calcium in Summerbell are irrelevant, and the Wikipedia citation is not prior art because the website

is continually updated. As previously explained and repeated in prior responses, Summerbell's diet is based on following a simple and easy-to-adhere-to diet that is not boring and monotonous. Summerbell does not teach or suggest the claimed method involving calcium inducing a metabolic change. In addition, one skilled in the art would not modify Summerbell because there is no reasonable expectation of success, because Summerbell indicates that the milk-only diet "will cease to be novel and compliance will fall."

Furthermore, because Summerbell offers no basis for concluding that the weight loss is attributable to the calcium in milk, replacing milk with other calcium-containing foods could not be "an obvious expedient," contrary to the Examiner's argument.

No other references are cited to cure the above-noted defects in Summerbell. Accordingly, Applicants request that this rejection be withdrawn.

#### **Claim Rejection – 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected claims 1-7, 10-17 and 19-22 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention. The Examiner contends that "[i]n claims 1, 10, 19, the phrase 'below ad lib in a range of about 200 to about 2500 kcal per day' is unclear." The Examiner asks "[i]s the implication here that 'ad lib' is a caloric intake that can exceed the claimed range?" Applicants traverse.

"Ad lib" and "below ad lib" are well-defined terms that pose no issues under § 112 second paragraph. As set forth in the specification, the caloric intake of an individual may be unmodified or ad lib and it may be desirable to reduce the caloric intake of the individual as part of the dietary plan (e.g., page 9, lines 3-9). Ad lib is defined as "without restraint or limit" (Merriam-Webster Online Dictionary <<http://www.m-w.com/cgi-bin/dictionary>> visited January 11, 2008). It is commonly understood in the field of nutrition that there are two practices of energy intake, e.g., food, drinks or calories, either (1) ad lib or (2) restricted. Ad lib is a commonly used term that is understood to be the unrestricted intake of food or calories available to the point of satisfaction. Restricted diets may include a variety of diets, including for example, restricting caloric intake. As is readily apparent from the specification, the restriction of unmodified or ad lib caloric intake may be slight or more

extensive based on whether the individual is maintaining or reducing body weight. Thus, "ad lib" and "below ad lib" are sufficiently definite terms for the purposes of § 112, second paragraph.

Furthermore, Applicants submit that it is irrelevant whether "ad lib" can exceed the claimed range, because the claim recites "below ad lib." The claim makes clear that the claimed dosing is both "below ad lib" and "in a range of about 200 to about 2500 kcal per day." Thus, the rejection for indefiniteness should be withdrawn.

In view of the foregoing, Applicants respectfully request that the rejection for indefiniteness be withdrawn.

#### **Claim Rejection – 35 U.S.C. § 102(a)**

The Examiner has rejected claims 1-7, 10-17 and 19-22 under 35 U.S.C. § 102(a) as being unpatentable over Zemel et al., FASEB Journal, 14(9), 1132-8 (June 2000). Applicants respectfully traverse.

In view of the attached inventor Declaration under 37 C.F.R. § 1.132, it is respectfully submitted that Zemel et al., is not prior art to the invention and that the publication disclosure was derived from the work of the inventors.

The present claims are entitled to the priority of Application No. 09/654,357 ("the '357 application"), filed on September 1, 2000, now U.S. Patent 6,384,087 ("the '087" patent).

As set forth in the attached Declaration, the Zemel et al., article is not prior art and is based on the inventors' own work. Applicants respectfully request that the rejection based on the Zemel et al., article be withdrawn. See MPEP §§ 715.01(c) and 716.10.

#### **Claim Rejection – 35 U.S.C. § 112, First Paragraph**

The Examiner has rejected claims 1-7, 10-17 and 19-22 under 35 U.S.C. § 112, first paragraph for failure to comply with the written description requirement. Applicants respectfully traverse because the specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed. MPEP § 2163.

The Examiner argues that the claim amendments stating “at least about 773 mg per day” and “at least about 57 servings of dairy per month” “introduce new matter into the claims” when compared with Table 4 on page 18 of the specification. According to the Examiner, “[b]ecause the limitation of ‘at least about’ with respect to both 773 and 57 provides for variation (e.g., 10% of 773 or 57) that is greater than that provided for in Table 4,” the Examiner contends that these claim elements introduce new matter.

Applicants disagree with the Examiner’s contention that the phrase “at least about” provides for variation of about 10% from the recited values, a statement for which the Examiner provides no authority.

In addition, Applicants disagree with the Examiner’s apparent suggestion that only Table 4 provides written description support for the claim elements at issue. Nevertheless, contrary to the Examiner’s arguments, Table 4 itself provides written description support for the full scope of these claim elements.

The Examiner apparently overlooks the clear fact that each value cited by the Examiner represents a mean, and the variability in the data supports the use of the term “about.” For example, Table 4 discloses that, for the third quartile of calcium and dairy consumption, the mean daily intake of calcium is 773 mg calcium per day, and the standard error of the mean (SEM) is  $\pm 28$ . The SEM is a measure of the variability of the data within a given range. Here, an SEM of plus or minus 28 means that the actual mean intake is probably within plus or minus 28 of the stated mean of 773 (i.e., about 4%). See [http://www.graphpad.com/help/prism5/prism5help.html?stat\\_standard\\_deviation\\_and\\_standard.htm](http://www.graphpad.com/help/prism5/prism5help.html?stat_standard_deviation_and_standard.htm) (visited January 16, 2008). Table 4 also discloses that the mean number of dairy servings consumed per month for this quartile is 57.2, with an SEM of  $\pm 1.0$ . These ranges around the mean provide written description support for the term “about.”

Likewise, for the fourth quartile of calcium and dairy consumption, Table 4 discloses that the mean daily intake of calcium is 1346 mg calcium per day, and the SEM is  $\pm 113$ . Table 4 also discloses that the mean number of dairy servings consumed per month for this quartile is 102.8, with an SEM of  $\pm 2.8$ . These ranges around the means provides written description support for the term “about.”

In view of the foregoing, Table 4 provides ample written description for the claim terms “at least about 773 mg calcium per day” and “at least about 57 servings of dairy per month,” such that one skilled in the art would reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. Accordingly, Applicants request that the rejection based on § 112 first paragraph be withdrawn.

### **Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-7, 10-17 and 19-22 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Dated: Feb. 13, 2008

DC2/924772

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